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## CERTIFICATE

This certificate is issued in support of an application for Patent registration in a country outside New Zealand pursuant to the Patents Act 1953 and the Regulations thereunder.

I hereby certify that annexed is a true copy of the Provisional Specification as filed on 18 March 2004 with an application for Letters Patent number 531829 made by David Peter Shaw.

Dated 8 April 2005.



Neville Harris  
Commissioner of Patents, Trade Marks and Designs



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PROVISIONAL SPECIFICATION

Method and Apparatus for the Treatment of Sleep Apnoea and Snoring

I, David Peter SHAW, of Cossars Road, Tai Tapu, R.D. 2, Christchurch, New Zealand,  
a New Zealand citizen, do hereby declare this invention to be described in the  
following statement:

1 (followed by 1a)

Title: Method and Apparatus for the Treatment of Sleep Apnoea and Snoring

Technical Field

5 The present invention relates to a method and apparatus for the treatment of sleep apnoea and snoring.

Background Art

10 Sleep apnoea is a condition of failing to breathe during sleep. The breathing process is complex and requires the coordination of many muscles within the body:- the diaphragm, the intercostal muscles, and the chest wall muscles. In addition, the muscles associated with the mouth and the upper airway have to be coordinated so that there is no obstruction to the airflow.

15

Failure to breathe may be due to:

20 a) A reduction in the tone of the pharyngeal muscles, so that these muscles are not retracted to allow the unimpeded entry/exit of air, or obstruction to the passage of air caused by a large tonsils or adenoids, or by an abnormally large tongue or small jaw (obstructive sleep apnoea);

b) The diaphragm and chest muscles temporarily ceasing to work, probably as result of a disturbance in the brain's control of breathing (central sleep apnoea);

c) A combination of (a) and (b).

25

Sleep apnoea affects approximately 2% of the population. Severe sleep apnoea is potentially serious:- it is known to be a factor in high blood pressure, heart failure, heart attacks and strokes. Further, a sufferer from sleep apnoea may be excessively sleepy during the day, and may fall asleep while driving or trying to work and/or may 30 suffer from poor memory and concentration.

Sleep apnoea caused by structural problems such as large tonsils or adenoids or by an abnormally large tongue or small jaw may be treated surgically. Sleep apnoea caused by non-structural problems often is treated by continuous positive airway 35 pressure (CPAP):- compressed air is forced into the sleeper's airway via a mask worn

over the nose. Since this treatment has to be given for the full sleeping period, every night, and the CPAP device is noisy and the mask is uncomfortable, the treatment is unpleasant both for the patient and his or her immediate family.

5

Snoring often is associated with obstructive sleep apnoea, but may occur independently of sleep apnoea. Although snoring is a minor problem compared to sleep apnoea, a persistent loud snorer can cause severe sleep disruption in any one trying to sleep in the same room, and there are no reliable treatments for snoring unless the snoring is caused by a structural problem (see above) which can be treated surgically.

10

#### Disclosure of Invention

15 It is therefore an object of the present invention to provide a method and apparatus for the treatment of sleep apnoea and snoring which overcomes the drawbacks of the present non-surgical treatments and provides a viable alternative to present treatments.

20 The present invention provides a method of treating sleep apnoea and/or snoring which includes the steps of:-

- a) Providing a sensor adapted to detect the condition to be treated;
- b) Providing apparatus for electrically stimulating a selected nerve;
- 25 c) Connecting said stimulation apparatus to said selected nerve;
- d) Connecting said sensor to said stimulation apparatus such that when said sensor detects the condition to be treated, said stimulation apparatus is activated.

30 The present invention further provides apparatus for treating sleep apnoea and/or snoring which includes:-

- a) A sensor adapted to detect the condition to be treated;
- b) Apparatus for electrically stimulating a selected nerve;
- 35 the sensor being connected to the apparatus such that when the sensor detects the condition to be treated, said apparatus is activated.

The type of sensor used naturally depends upon the condition to be treated:- in the case of snoring, an audio sensor or vibration sensor set up to detect noises on the normal wavelength of snoring noise could be used.

5

In the case of sleep apnoea, the sensor would be one capable of sensing the failure of normal respiration:- that is, either the cessation of breathing (as in central sleep apnoea) or the irregular rhythm which occurs when there is attempted breathing but with no airflow (as in obstructive sleep apnoea). Suitable sensors may include  
10 external or internal sensors; for example, external mechanical or electrical devices to measure chest wall movement, (e.g. thoracic impedance) or internal devices for transvenous sensing of respiration (such as impedance sensing) or for detecting physical deformation, (e.g. transvenous fibre optics), or for detecting sound or vibration.

15

#### Brief description of Drawing

By way of example only, preferred embodiments of the present invention as applied to the treatment of sleep apnoea is described in detail with reference to the  
20 accompanying drawings, in which:-

Fig.s 1 and 2 show diagrammatic cross-sections through the chest of a patient with first and second embodiments, respectively, of the present invention.

#### Best Mode for Carrying out the Invention

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In a preferred embodiment of the present invention, as shown in Fig. 1, the treatment of sleep apnoea using the method and apparatus of the present invention is based on the premise that the afferent fibres of the phrenic nerve are integrated into the coordination of breathing.

30

The human body is designed so that every muscle or set of muscles has controlling nerves, and virtually every nerve has both afferent and efferent fibres. The afferent fibres feed back from the muscles to the brain, and the efferent fibres control the reaction of the muscles in response to the stimuli being processed by the brain. In  
35 breathing, the efferent fibres control the coordination of the diaphragm, the intercostal muscles, and the muscles of the chest wall; these coordinate with the muscles of the

upper airways (the pharyngeal muscles) which appropriately restrict or relax. The afferent fibres feed back to the brain information on muscle position and chest wall position. The brain must also integrate a timing mechanism for the frequency of breaths, which includes monitoring the activity level and the carbon dioxide and 5 oxygen levels so that respiration is increased or decreased as appropriate.

The phrenic nerve is one of the nerves associated with the muscles used in breathing. It is believed that electrical stimulation of the afferent fibres of the phrenic nerve during an episode of sleep apnoea will cause the brain to realise that a breath should be 10 taken, and thus initiate the coordination of breathing, including increasing tone in the pharyngeal muscles to open the airway.

Particular reference is made to the phrenic nerve because the technology for stimulation of the phrenic nerve is already developed (for cardiomyoplasty, phrenic 15 nerve stimulation in spinal patients, and spinal stimulation) and because the phrenic nerve is easy to identify, for fitting the apparatus as described below. However, it must be emphasised that the method and apparatus of the present invention are not limited to use with the phrenic nerve:- other nerves associated with the breathing process could be used instead.

20

Referring to the Fig. 1 of the drawing, part of the phrenic nerve 2 is shown, extending alongside the heart 3.

A sensor in the form of a transvenous lead 10 is inserted down the superior vena cava 25 of the patient into the right ventricle. A second lead 12 is attached to the phrenic nerve; two possible attachment points 12a/12b are shown. The other ends of the leads 11 and 12 are connected to a small generator/computer 13 which could be mounted externally on the patient, but which preferably is mounted in a subcutaneous pocket in the patient in a similar manner to a heart pacemaker, as shown.

30

In the event that the sensor 10 detects either the failure of respiration, or those movements which suggest obstruction of the airway, then the sensor 10 activates the generator/computer 13 which in turn creates an electrical stimulation of the phrenic nerve via the lead 12. The stimulation of the phrenic nerve causes a contraction of the 35 diaphragm and stimulation of the afferent phrenic nerve fibres to the brain. It is believed that this will cause the brain to initiate a coordinated breath action, which

includes increasing the tone of the pharyngeal muscles and thus opening the airway.

It will be appreciated that, since stimulation of the phrenic nerve will in turn stimulate the brain, and will increase the tone of the pharyngeal muscles, this technique will be  
5 effective in treating either or both central sleep apnoea and obstructive sleep apnoea.

As described above, other types of the sensor may be used.

Fig. 2 shows the use of a vibration sensor 14, for detecting the abnormal vibration  
10 caused by snoring. The sensor 14 is located adjacent the trachea 15 of the patient, and is connected to a generator/computer 13 which also is connected to a lead 12, attached to the phrenic nerve 2. If the vibration sensor is activated by the vibration of snoring, the generator/computer 13 causes electrical stimulation of the phrenic nerve via the lead 12, as described with reference to Fig. 1.

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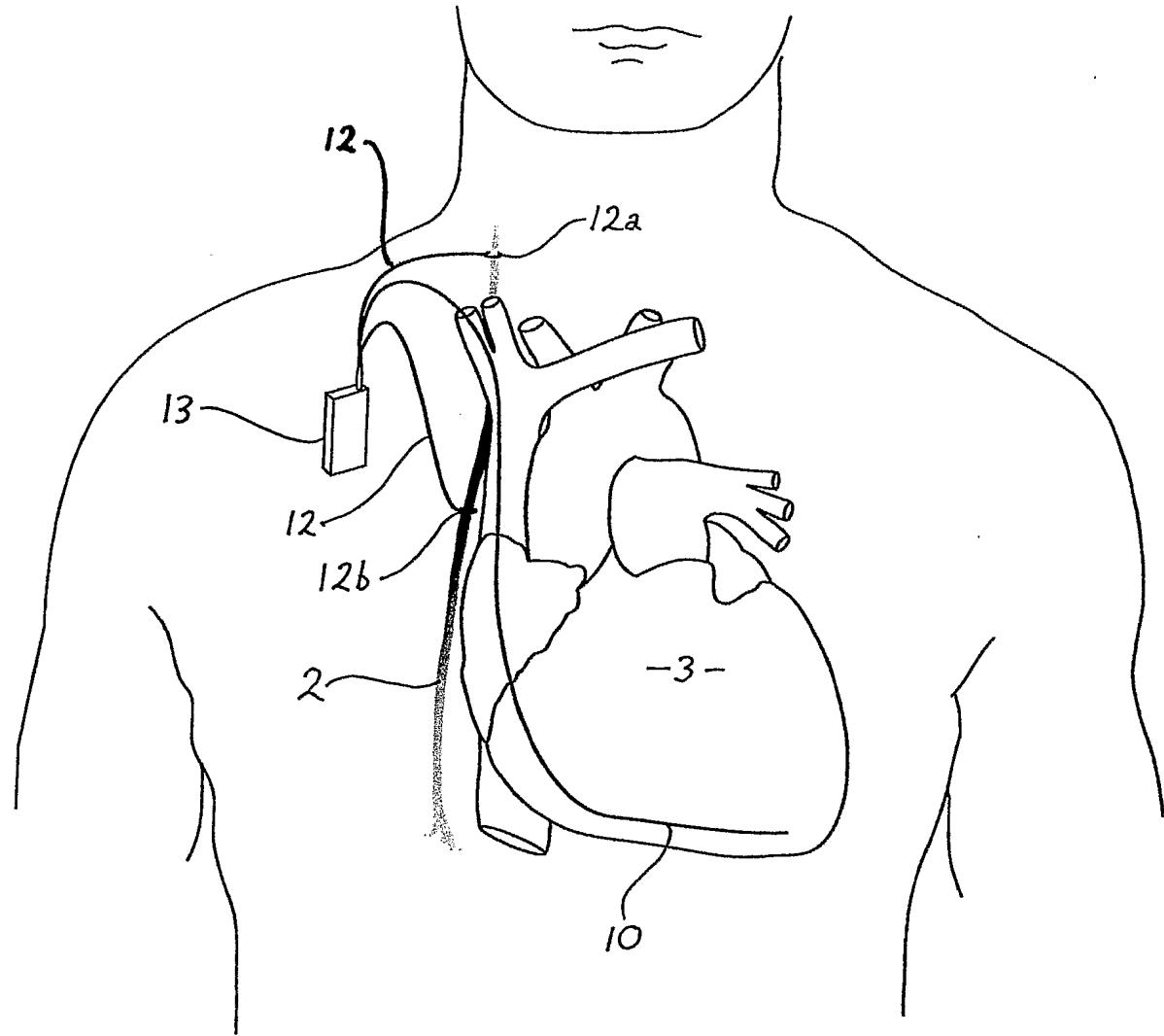


Fig 1

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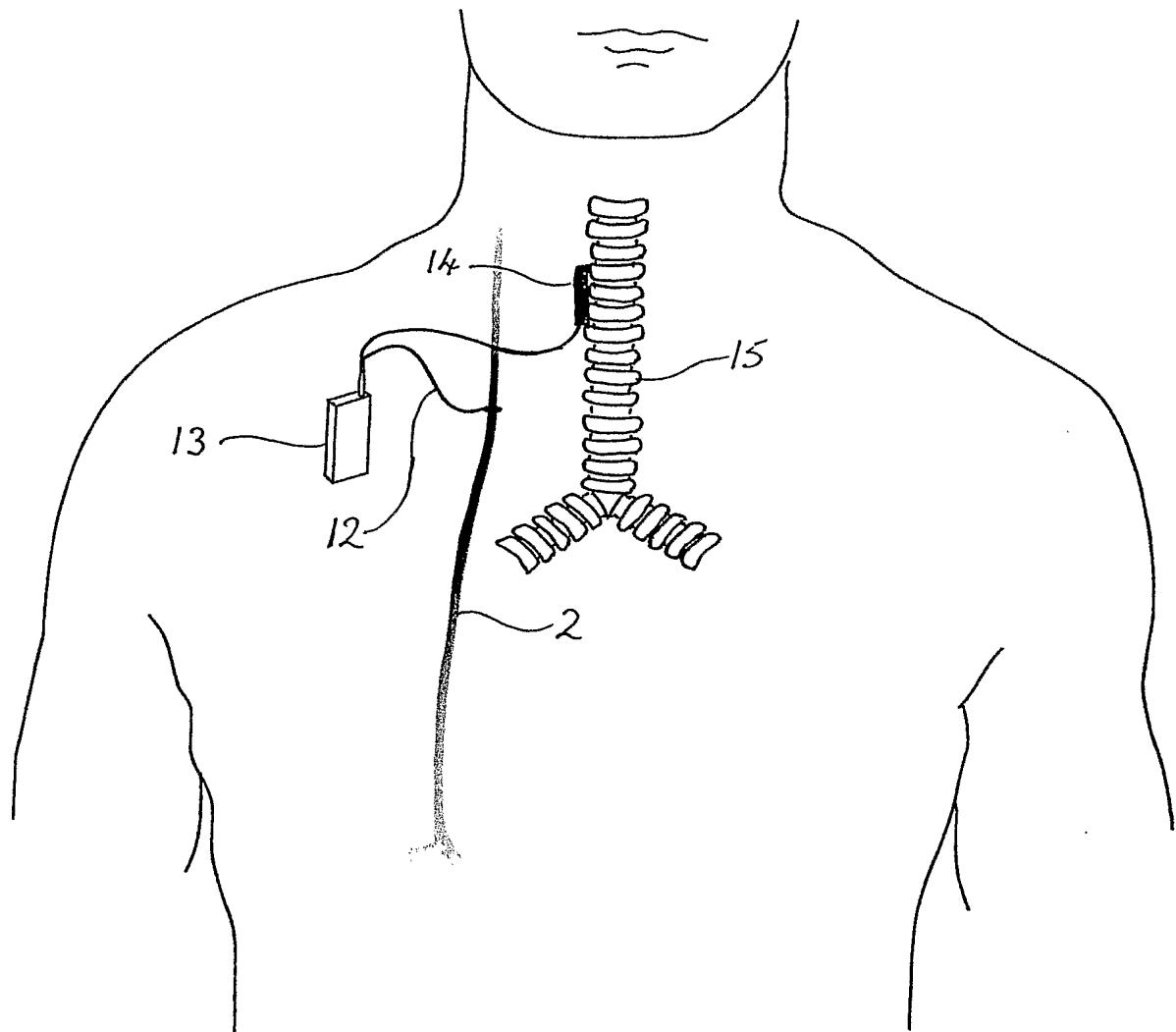


Fig 2